

# Appendix 1

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## APPENDIX 1

### **Information for the Patient** (for Combined Oral Contraceptives)

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#### **1. About Birth Control Pills (“the Pill”)**

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- This pamphlet is about the “combined” birth control pills (“the Pill”).  
The combined Pill has two hormones to prevent pregnancy--estrogen and progestin.
- This pamphlet has important information about [NAME] and how to take the Pill safely and effectively.
- Please read all of this pamphlet before you start taking your first pack of Pills.  
Check it again any time you have a question.
- **Talk to your doctor or clinic staff:**
  - if you have any questions about anything this pamphlet says.
  - if you are worried about taking the Pill for any reason.

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#### **2. How does the Pill work?**

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**The Pill can prevent pregnancy in 3 ways:**

1. The Pill keeps the egg (ovum) from leaving the ovary (ovulation).
2. It can make it hard for the sperm to get to the egg (fertilization).
3. The Pill can make it harder for the egg to attach to the uterus/womb (implantation),

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#### **3. How well does the Pill work?**

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**3.1 The Pill prevents pregnancy best:**


- if you never miss a pill
- if you miss 2 or more [color(s)] active Pills in a row, use condoms until you’ve been back on the [color(s)] Pills for 7 days in a row.

**3.2 If you take one birth control pill every day, it prevents pregnancy very well.**

Less than 1 out of every 1000 women (less than 0.1%) who take the Pill every day will get pregnant in their first year on the Pill.

**3.3 Your chance of getting pregnant goes up every time you miss more than one pill.**

- 3.4. This list shows how well different methods prevent pregnancy, in typical use. The only birth control methods that work better than the Pill are Norplant, the IUD, Depo-Provera (“the shot”) and Lunelle (“the 1-month shot”).

<i>Works best</i>	<i>Method</i>	<i>Chance of getting pregnant in the first year of use</i>
	Norplant	1%
	IUD	1%
	Depo-Provera (“the shot”	1%
	Lunelle (the 1 -month shot”	*
	<b>“The Pill”</b>	<b>5%</b>
	Male Condom	14%
	Diaphragm	20%
	Female Condom	21%
	Not having sex for long periods of time (periodic abstinence)	25%
	Not having sex at certain times of the month (“calendar method” or natural family planning)	25%
<i>Works Least</i>	Not using any kind of birth control	<b>85%</b>

*Adapted from Contraceptive Technology, 1998*

*\* How well Lunelle works in typical use is not yet known.*

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## 4. What are some advantages of taking the Pill?

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- 4.1 **Your periods may be more comfortable:**
- they may be more regular
  - they may be shorter
  - you may have less bleeding
  - you may have less cramps or pain.
- 4.2 **There is less chance of having:**
- a pregnancy outside of the uterus/womb (ectopic pregnancy)
  - a lump in the ovary (ovarian cyst)
  - a not enough iron in the blood (anemia).
- 4.3 **While you are on the Pill and for many years after you stop taking it, there is less chance of getting :**
- cancer in the ovaries (ovarian cancer)
  - lumps in the breast that are not cancer (benign breast tumors)
  - cancer of the uterus (endometrial cancer).

#### 4.4 ALSO...

- taking the Pill keeps bones strong (helps prevent osteoporosis).
- taking the Pill may help prevent pimples (acne).

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### 5. Who should not take the Pill?

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**The Pill is very safe. But if you have any of the medical problems listed below, it is very important to talk to your doctor or clinic staff.**

#### 5.1 **You should not take the Pill if you:**

- are more than 35 years old and you smoke
- are already pregnant or you think you might be pregnant
- have just had major surgery that keeps you in bed for a long time
- are allergic to anything in the Pills.

#### 5.2 **You should not take the Pill if you now have:**

- very high blood pressure (severe, uncontrolled hypertension)
- breast cancer
- very high blood sugar (severe diabetes) if the blood vessels are not normal
- any kind of liver disease.

#### 5.3 **You should not take the Pill if you've ever had:**

- very bad headaches that also make it hard for you to see clearly
- a heart attack or a stroke
- blood clots in your lungs (pulmonary embolism)
- blood clots in your eyes or your legs (thrombosis)
- breast cancer.

#### 5.4 **If your doctor or clinic staff thinks the following problems are not too serious, it is still safe to take the Pill if you have:**

- high blood pressure (hypertension) and you take medicine for it
- high blood sugar (diabetes) if your blood vessels are normal
- bad headaches (such as migraines) if they don't change your vision
- bleeding from your vagina that is not your menstrual period.

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## 6. Can the Pill cause medical problems?

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Most healthy women do not get medical problems because they take the Pill. However, there is a small chance that the Pill can increase the chance of having:

6.1 **Heart attack or stroke [only] if you also have:**

- very high blood pressure (severe hypertension)
- high cholesterol
- high blood sugar (diabetes).
- These problems only last as long as you are on the Pill.
- Most important: If you smoke and you are over 35 years old, you are much more likely to have a heart attack or a stroke.

6.2 **Blood clots in the veins**

6.3 **Breast cancer**

- The chance getting breast cancer is low but the chance of finding it is a little higher while on the Pill.
- Any effect the Pill might have on breast cancer goes down after stopping the Pill.

6.4 **Cancer of the cervix**

- Cervical cancer is very rare. It is not known yet whether the Pill has any effect on cancer of the cervix (the opening to the uterus).

6.5 **Gall bladder disease**

- If you already have gall bladder disease, the Pill could make the problem worse.

6.6 **Liver cancer**

- The Pill can increase the chance of getting liver cancer. Liver cancer is very rare.

\*\*\*\*\***WARNING SIGNS**\*\*\*\*\*

**Call your doctor or clinic as soon as possible if you get:**

- a very bad headache that also makes it hard for you to see clearly
- a very bad pain in your chest, your stomach (abdomen) or your legs.

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## 7. What side effects can I get from the Pill?

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### 7.1 You may get one or more side effects while taking the Pill.

- These side effects are almost never dangerous, but if they worry you, check with your doctor or clinic.
- Keep taking the Pill until you can talk to your doctor or clinic staff

### 7.2 Bleeding Side Effects

- You may have some spotting or light bleeding between periods, especially after you miss any Pills.

### 7.3 Other Side Effects

It is not always clear whether the Pill causes these side effects. Many of them go away in the first 3 months.

- The most common side effects are:
  - nausea or upset stomach
  - headaches
  - tender or sore breasts.
- Less common side effects are:
  - vomiting
  - mood changes
  - weight gain
  - less interest in sex
  - dizziness
  - brown spots on the face (melasma)
  - vaginal yeast infection
  - swelling (fluid retention)
  - dry eyes.

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## 8. Can I take the Pill with other medicines?

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### 8.1 If you are taking other medicines, tell your doctor or clinic staff.

- Taking antibiotics while on the Pill does not make it easier to get pregnant.
- A few medicines can make the Pill less effective, especially certain medicines for seizures (epilepsy), and tuberculosis (TB).
- St. John's Wort, an herb to reduce depression, can cause spotting or bleeding between periods.
- Any time you get a prescription from another doctor's office or clinic, tell them that you are taking the Pill. The Pill can make some medicines less effective.

- 8.2 **If you have lab tests for any reason, be sure to say that you are taking birth control pills.** The hormones in the Pill can change the results of some lab tests.

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## 9. STDs (Sexually Transmitted Diseases)

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- 9.1 **The birth control pill does not protect against HIV (the virus that causes AIDS) or any other STD.**
- 9.2 **Use a condom every time you have sex if there is any chance you could get HIV (the AIDS virus) or any other STD.**

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## 10. What should I do when I start taking the Pill?

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- 10.1 **Check your Pill pack. Is it a 28-day pack or a 21-day pack of Pills?**

- The 28-day Pill pack has:
  - 21 [color(s)] active hormone pills to take for the first 3 weeks
  - 7 [color] reminder pills (with no hormones) to take the 4<sup>th</sup> week.
- The 21-day pill pack has:
  - 21 [color(s)] active hormone pills to take for the first 3 weeks
  - The 21-day pack does not have any Pills to take during the 4<sup>th</sup> week.

- 10.2 **Check this picture of the Pill pack to see:**

- which Pill to take first
- what direction to take the Pills in
- the week numbers and Pill colors.

***[MANUFACTURER: INSERT PILL PACK PICTURE HERE]***

- 10.3 **Decide with your doctor or clinic staff when to start your first pack of Pills.**

- You can begin taking the Pill any time but it is usually easier to pick a specific day. For example:
  - the first Sunday after your period starts
  - or the first day of your menstrual period.
- Use condoms until you have taken [color(s)] active Pills for 7 days in a row unless you start on the first day of your period.

- 10.4 **If you've had a miscarriage or an abortion, talk to your doctor or clinic staff about when you can start taking the Pill.**

- 10.5 **Take one Pill every day until the pack is empty.**
- Take that Pill at the same time every day.
  - Do not skip taking any Pills:
    - even if you have some spotting of blood between your periods
    - if you have other side effects, such as nausea or an upset stomach.
- 10.6 **Your chance of getting pregnant goes up every time you miss more than one Pill.**
- Get your next pack of Pills before you need them so you can start every pack on time.
  - Keep condoms in case you do start a Pill pack late or you miss two or more Pills in a row.

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## 11. What should I do if I miss any Pills?

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- 11.1 **If you miss one of the [color(s)] active Pills:**
- Take the missed Pill as soon as you remember.
  - Take the next Pill at the regular time. This means you may take two Pills in one day.
  - Keep taking one Pill each day, as usual.
  - You do not need to use condoms to prevent pregnancy if you miss just one Pill.
- 11.2 **If you miss two or more of the [color(s)] active Pills in a row, or if you start your next Pill pack two or more days late:**
- Take one pill now.
  - Don't try to make up the other [color(s)] Pills you missed. Throw them out.
  - Keep taking one [color(s)] active Pill every day until they are gone
  - Use condoms or do not have sex until you have been back on the [color(s)] active Pills for 7 days in a row.
  - Go straight to the next pack after you finish the [color] active Pills. You do not need to take the 7 [color] reminder Pills.
- 11.3 **If you missed two or more [color(s)] of the active Pills, and then had sex without using condoms in the next 7 days:**
- Call your doctor or clinic as soon as possible.
  - They can prescribe Emergency Contraceptive Pills (ECPs), sometimes called Morning After Pills. [See *Section 13 below.* ]
- 11.4 **If you are using a 28-day pack and forget to take any of the 7 [color] reminder Pills:**
- Throw out the [color] reminder pills that you missed.
  - Keep taking one [color] reminder Pill every day until it is time to start a new Pill pack.
  - You do not need to use condoms to prevent pregnancy if you missed only the reminder Pills.



- 11.5 **If you are using a 21-day pack, you will not be taking any Pills during the 4<sup>th</sup> week:**
- Once you have finished your 21 [color] Pills, wait 7 days before starting the next pack. For example, if you finish on Saturday, wait one week, and then start the next pack on Sunday.
- 11.6 **If you have very bad vomiting for two days in a row, and the vomiting is in the first 3 hours after taking your Pill:**
- Call your doctor or clinic for advice.
  - Use a condom if you have sex during the next 7 days.

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## **12. Important reminders about missed Pills**

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- 12.1 **Any time you miss 2 or more [color(s)] active Pills in a row, or you start a pack late:**
- Use condoms or do not have sex until you have been back on [color(s)] active Pills for 7 days in a row.
  - If you do not use condoms after missing 2 or more Pills, call your doctor or clinic as soon as possible about getting ECPs (Emergency Contraceptive Pills) *[See Section 13 below]*
- 12.2 **Any time you are not sure what to do, or if you have any other questions, **CALL** your doctor or clinic.**

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## **13. Emergency Contraceptive Pills (ECPs)**

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- ECPs are sometimes called “Morning After Pills.”
- If you have sex without using a condom after you have missed 2 or more Pills in a row, ECPs can lower your chance of getting pregnant.
- ECPs work best if you take them as soon as possible, and within 3 days of having unprotected sex.
- ECPs do not work if you are already pregnant.
- ECPs are safe and easy to use.

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## **14. What if I miss my monthly period?**

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- 14.1 **If you miss one period:**
- If you have taken your Pill every day or used condoms every time you had sex, you are probably not pregnant
  - If you have not taken your Pill every day and have not used condoms every time you had sex, call your doctor or clinic for a pregnancy test.

**14.2 If you miss two periods in a row:**

- Call your doctor or clinic for a pregnancy test, even if you have taken your Pills every day or used condoms every time you had sex.

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**15. What if I want to stop taking the Pill or change birth control methods?**

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**15.1 If you want to stop taking the Pill or change to another method:**

- Check with your doctor or clinic staff before you make any changes.
- If there is a chance that you will start taking the Pill again in the next few months, it is a good idea to keep taking the Pill every day.
- If you want to stop using birth control pills, to get pregnant, for example, waiting until you finish your pack will cause the least change in your monthly cycle.
- If you only want to change the kind of birth control pill you use, wait until you start your next pack to start the new Pills.

**15.2 If you change to the Pill from another method of birth control:**

- Keep using the other method until the day you want to start taking the Pill.
- Follow the instructions for “When to Start Your First Pack of Pills” [See *section 10.3*]

**15.3 If you change from the Pill to another method of birth control, wait until you finish your Pill pack to start the new method.**

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**16. What if I want to get pregnant?**

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**If you want to get pregnant, just stop taking the Pill. (See section 15. 1)**

- Having been on the Pill does not make you less likely to get pregnant once you stop, but it may take a little longer.

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**17. Does the Pill cause birth defects?**

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**The Pill does not cause birth defects.**

- Even if you are taking the Pill in the first 3 months you are pregnant (for example, before you know you are pregnant) your baby should be fine.
- If you find out that you are pregnant, stop taking the Pill.

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## 18. What if I just had a baby?

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- If you are not breast feeding, you can start the Pill after your baby is 3 weeks old.
- If you are breast feeding,
  - Do not start taking the Pill until your baby is at least 6 weeks old.
  - It is safest to wait until you have finished breastfeeding to start taking the Pill. Use another birth control method instead.

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## 19. What if a child takes any of the Pills?

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Taking birth control pills by mistake probably won't cause any problems, even in children, *but...*

- Call your child's doctor or clinic if you are worried.
- Keep all medicines where children cannot reach them.

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## 20. Where should I keep the Pills?

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- Keep the Pills where you will remember to take them at the same time every day.
- Keep the Pills at room temperature.

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## 21. What if I have other questions?

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- You can get information from [ 1 -888-XXX-XXXX] or [WEBSITE(s)].
- You can ask your doctor or clinic staff for the more detailed "Labeling for Healthcare Providers."

**Remember, you can always call your doctor or clinic if you have questions.**